6109332490

LISTING OF THE CLAIMS

- 1. (Previously Presented) A pharmaceutical composition comprising a therapeutically effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceuticallyacceptable salt thereof, substantially free of (S,R'), (S,S')-amphetaminil, and at least one pharmaceutically-acceptable carrier, diluent, excipient or additive.
- 2. (Original) A controlled release formulation comprising the pharmaceutical composition of claim 1.
- 3. (Original) An immediate release formulation comprising the pharmaceutical composition of claim 1.
- 4. (Original) An oral dosage form comprising the pharmaceutical composition of claim 1 consisting of about 0.1 to about 100 mg of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof.
- 5. (Original) The dosage form of claim 4 consisting of about 1 to about 50 mg of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof.
- 6. (Original)The pharmaceutical composition of claim 1 wherein said (R,R'),(R,S')amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 90% of the weight of total amphetaminil.
- 7. (Original) The pharmaceutical composition of claim 1 wherein said (R,R'),(R,S')amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 95% of the weight of total amphetaminil.
- 8. (Original) The pharmaceutical composition of claim 1 wherein said (R,R'),(R,S')amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 99% of the weight of total amphetaminil.
- 9. (Canceled) A method for prophylaxis or treatment of a human condition or disease requiring or benefiting from a central nervous stimulant comprising administering to said human an effective amount of a pharmaceutical composition comprising (R,R'),(R,S')amphetaminil sulfate or another pharmaceutically-acceptable salt thereof, substantially free of (S,R'), (S,S')-amphetaminil.
- 10. (Canceled) The method of claim 9 wherein said administering is parenteral, transmucosal or transdermal.

- 6109332490
- 11. (Canceled) The method of claim 10 wherein said administering is orally, nasally, or rectally.
- (Canceled) The method of claim 10 wherein said administering is intra-arterial, intravenous, intramuscular, intradermal, subcutaneous, intraperitoneal, intraventricular, or intracranial.
- 13. (Canceled) The method of claim 9 wherein the amount administered is about 0.1 to about 100 mg daily.
- 14. (Canceled) The method of claim 13 wherein said amount administered is about 1 to about 50 mg daily.
- 15. (Canceled) The method of claim 14 wherein said amount administered is from one to about four unit doses per day.
- (Canceled) The method of claim 15 wherein said amount administered is one or two unit doses per day.
- 17. (Canceled) The method of claim 5 wherein the amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 90% of the weight of total amphetaminil.
- 18. (Canceled) The method of claim 17 wherein the amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 95% of the weight of total amphetaminil.
- 19. (Canceled) The method of claim 17 wherein the amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof is greater than about 99% of the weight of total amphetaminil.
- 20. (Canceled) The method of claim 9, wherein the amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof, substantially free of (S,R'),(S,S")-amphetaminil, is administered together with a pharmaceutically-acceptable carrier, diluent, excipient, or additive.
- 21. (Canceled) The method of claim 9, wherein said condition or disease is narcolepsy, attention deficit hyperactivity disorder (ADHD), depression, Parkinson's disease, cognitive dysfunction, or Alzheimer's disease, renal dysfunction, asthma, obesity, nicotine withdrawal, hypotension, apathy, potentiating activity of a conventional antidepressant,

05/20/2009 21:11

- potentiating an opiate for pain control or reduced energy associated with chemotherapy or radiation therapy.
- (Canceled) The method of claim 9 wherein said condition or disease is amenable to treatment by preferential activation of mesolimbic-mediated behavior.
- 23. (Canceled) A pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof for the treatment or prevention of a disorder benefiting from or requiring a central nervous system stimulant, substantially free of (S,R'), (S,S')-amphetaminil, and at least one pharmaceutically-acceptable carrier, diluent, excipient or additive.
- 24 (Canceled) The pharmaceutical composition of claim 23, wherein the disorder is selected from the group consisting of narcolepsy, attention deficit hyperactivity disorder, depression, Parkinson's disease, cognitive dysfunction, renal dysfunction, asthma, obesity, nicotine withdrawal, hypotension, apathy, pain and reduced energy associated with chemotherapy or radiation therapy.
- 25. (Withdrawn) A method for preparing (R,R'),(R,S')-amphetaminil substantially free of (S,R'), (S,S')-amphetaminil, the method comprising obtaining a racemic material comprising (R,R'),(R,S')-amphetaminil and purifying said (R,R'),(R,S')-amphetaminil so that the (R,R'), (R,S')-amphetaminil is substantially free of (S,R'), (S,S')-amphetaminil, wherein the (R,R'),(R,S')-amphetaminil is converted to its sulfate salt or another pharmaceutically-acceptable salt thereof to minimize degradation of the (R,R'),(R,S')-amphetaminil.
- 26. (Withdrawn) The method of claim 25, wherein the (R,R'),(R,S')-amphetaminil sulfate is purified by trituration.
- 27. (Withdrawn) The method of claim 25, wherein the (R,R'),(R,S')-amphetaminil sulfate is purified by a chiral analytical column by freeing the sulfate with an ammonium hydroxide solution followed by extraction with hexane and rapidly injecting (R,R'),(R,S')-amphetaminil salt in the column and recovering the (R,R'),(R,S')-amphetaminil and converting it to the sulfate salt.

- 28. (Canceled) (R,R'),(R,S')-amphetaminil substantially free of (S,R'), (S,S')-amphetaminil prepared by the method of claim 25.
- 29. (Canceled) The sulfate or another pharmaceutically-acceptable salt thereof of the (R,R'),(R,S')-amphetaminil of claim 28.
- 30. (Previously Presented) A pharmaceutical composition comprising an effective amount of (R,R'),(R,S')-amphetaminil sulfate or another pharmaceutically-acceptable salt thereof for the treatment of a disorder benefiting from or requiring a central nervous system stimulant, substantially free of (S,R'), (S,S')-amphetaminil, and at least one pharmaceutically-acceptable carrier, diluent, excipient or additive.
- 31 (Previously Presented) The pharmaceutical composition of claim 30, wherein the disorder is selected from the group consisting of narcolepsy, attention deficit hyperactivity disorder, depression, Parkinson's disease, cognitive dysfunction, renal dysfunction, asthma, obesity, nicotine withdrawal, hypotension, apathy, potentiating an opiate for pain control, and reduced energy associated with chemotherapy or radiation therapy.
- 32. (New) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition is administered at a dosage that is not about 0.1 mg/kg nor about 10 mg/kg.
- 33. (New) The pharmaceutical composition of claim 32, wherein the pharmaceutical composition is administered at dosage of about 1 mg/kg
- 34. (New) The pharmaceutical composition of claim 30, wherein the pharmaceutical composition is administered at a dosage that is not about 0.1 mg/kg nor about 10 mg/kg.
- 35 (New) The pharmaceutical composition of claim 34, wherein the pharmaceutical composition is administered at dosage of about 1 mg/kg